REMARKS

Claims 1-5 and 10 are currently pending.

Applicants acknowledge with thanks the withdrawal of the Examiner's objections to claim 5; to claims 3, 4 and 10 under 35 U.S.C. §112, first paragraph (scope of enablement), and to claims 1 and 5 under 35 U.S.C. §102 (anticipation by Abramowitz et al.).

Amendments to the Specification

As an initial matter, in the application as filed, the same sequence identifier was inadvertently used to describe more than one peptide sequence, for example, PCP-8, PCP-13 and PCP-13.8 in Table 1 are all identified as SEQ ID NO:1 even though the types of amino acids comprised by the peptides are different *(i.e.,* D- vs. L-amino acids). For reasons of clarity, therefore, please amend the sequence identifiers for several of the indicated peptides listed in Table 1 such that each peptide has a unique identifier. These amendments are fully supported by the application as filed, for example, in Table 1 which lists the sequences for the peptides and at page 14, lines 13-14, which indicates that L-amino acids are represented by small letters and D-amino acids by capital letters. Accordingly, Table 1 on page 14 of the application has been amended to reflect the new SEQ ID NOs.

In addition, the specification has been amended by the insertion of two paragraphs into the "Summary of the Invention" corresponding to new claims 1 and 2 in order to provide a summary commensurate in scope with the new claims.

Enclosed please find a Substitute Sequence Listing with the amended sequence identifiers which each describe one peptide sequence. Please substitute the originally filed Sequence Listing with the enclosed Substitute Sequence Listing.

Amendments to the Claims

Claim 1 has been amended to clarify that lowercase or small letters indicate L-amino acid conformations and capital letters indicate D-amino acid conformations. Also included are additional structural details. Support for these amendments may be found

throughout the specification, for example, at page 4, line 16 to page 5, line 8; at page 9, lines 31-34; at page 14, lines 13-14; and in Table 1.

Claim 2 has been amended to indicate a variant sequence and corresponding SEQ ID Nos and delete reference to the 88% homology. Support may be found throughout the instant specification, for example, in Table 1 and at page 15, lines 1 to 6. Please note that the amendments to claim 2 reflect amendments made to the sequence identifiers as described below.

Supplemental Information Disclosure Statement

Also enclosed is a supplementary information disclosure statement and Form 1449 citing references corresponding to a co-pending application (U.S. Serial No. 10/678,413).

35 U.S.C. §112 Rejections

The Examiner rejected claims 1-5 and 10, alleging that there is no support for the limitation "and provided that the antagonist is not native prostaglandin F2 receptor" recited in claim 1. In order to expedite prosecution of the instant application, applicants have amended claim 1 and removed the language "and provided that the antagonist is not native prostaglandin F2 receptor." Applicants, therefore, respectfully request reconsideration and withdrawal of the 35 U.S.C. §112, first paragraph rejection to claim 1 on this ground.

The Examiner rejected claim 2 alleging that there is no support for "88%" in the specification. Applicants have amended claim 2 to remove the reference to "88% homology." Claim 2, as amended, recites a peptide "consisting essentially of a variant sequence of any one of SEQ ID NOs:1, 4 to 11, 13, 14 or 15 in which one or more amino acid residues are substituted or deleted...." This amendment is fully supported by the specification as filed, as indicated above. Applicants, therefore, respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, first paragraph rejection to claim 2 on this ground.

35 U.S.C. §102 Rejections

The Examiner rejected claims 1 and 5 as being anticipated by Rehwald *et al.*, which discloses a mutant rat F2 receptor. The Examiner acknowledged that the cited prior art is

silent as to the sequence of the rat receptor, but has alleged that, in the absence of evidence to the contrary, this receptor comprises one of SEQ ID NOs:1 or 4-11.

Applicants respectfully traverse this rejection. Applicants respectfully remind the Examiner that in order to be anticipatory, a prior art document must disclose each and every element in a claim. Rehwald *et al.* (hereinafter referred to as "Rehwald") focuses on the role in ligand binding of His-81 in the second transmembrane domain of the rat FP receptor and describes mutant rat FP receptors with a single amino acid change at position 81. Not only does Rehwald not disclose the amino acid sequence of either the native or the mutant rat F2 receptors (as acknowledged by the Examiner), but Rehwald also does not disclose any antagonists of the FP receptor. Furthermore, there is no mention in Rehwald of pharmaceutical compositions comprising antagonists of the FP receptor as claimed in claim 5 of the instant application. Thus the Examiner's allegation that, absent evidence to the contrary, the mutant rat FP receptor described in Rehwald would comprise one of SEQ ID NOs:1 or 4-11 and that the mutant FP receptor would have antagonist activity, would appear to be based on the Examiner's belief that the claimed antagonists are inherently disclosed in Rehwald. Applicants respectfully direct the Examiner's attention to the MPEP at § 2112, which sets out the requirements for a rejection based on inherency and, specifically to § 2112, Part IV, which states

> "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic.... To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference" [emphasis added].

Claim 1, currently on file, is directed to an antagonist comprising one of SEQ ID NOs:1 or 4-11. Most of the sequences recited in claim 1 comprise D-amino acids, *i.e.* non-natural amino acids that would not be present in the naturally occurring receptor. An antagonist comprising any one of the sequences as recited in claim 1, therefore, could not be inherently disclosed by the description in Rehwald of a mutant rat FP receptor comprising a single amino acid change at position 81. Furthermore, the sequences recited in claim 1 are all based on a short

sequence derived from the human FP receptor, specifically ILGHRDYK. As is known in the art, the sequence of a particular protein frequently differs depending on which animal species the protein is isolated from. Thus, while a particular amino acid sequence present in the human FP receptor may be found in a rat FP receptor, it is not necessarily present in the rat FP receptor. In this respect, applicants would like to direct the Examiner's attention to Lake *et al.*, which shows an alignment of the amino acid sequence of the rat, mouse and human FP receptors (see Figure 3, at page 320) and clearly shows that there are a number of differences between the human and rodent sequences. In particular, applicants direct the Examiner's attention to amino acid residues 171-178 of the alignment where it can be seen that the rat and mouse sequences contain the amino acid sequence ILGHRDY**Q**, whereas the corresponding region of the human sequence is ILGHRDY**K**. Applicants strongly assert, therefore, that Rehwald does not disclose, explicitly or inherently, the subject matter of claims 1 and 5.

In order to expedite prosecution of the instant application, applicants have amended claim 1 to more clearly define the claimed antagonists as "consisting essentially of an amino acid sequence derived from the second extracellular loop of a prostaglandin F2 receptor." Applicants assert that it is well known in the art that prostaglandin F2 receptors consist of an N-terminal domain, seven transmembrane segments, three extracellular loops, three intracellular loops and a C-terminal domain. Accordingly, an antagonist consisting essentially of an amino acid sequence derived from the second extracellular loop would not include a full length FP receptor. Applicants, therefore, respectfully request reconsideration and withdrawal of the 35 U.S.C. §102 rejection to the claims on this ground.

35 U.S.C. §103

The Examiner rejected claims 1 and 5 as not being patentable over Lake *et al.* (FEBS 355) in view of Rehwald *et al.* (FEBS 443). It is the Examiner's belief that the antagonists of the present invention are obvious in light of Lake, which teaches the human and rat FP receptors, and Rehwald, which discloses a mutant rat FP receptor.

Applicants respectfully traverse this rejection. As discussed above, Rehwald does not disclose any antagonists of the FP receptor or any sequences comprising D-amino acids. Moreover, there is no teaching or suggestion in Rehwald regarding antagonists of the FP

receptor. With respect to Lake, even though this reference discloses the sequences of the human, mouse and rat FP receptors, Lake does not disclose any antagonists of the FP receptor. Lake is concerned exclusively with the production of cell lines that would express a homogenous population of the full length FP receptor, which can be used to screen drugs and study FP receptors (see Lake at page 324, right hand column, last paragraph). Nowhere in Lake is there any suggestion that the disclosed sequences of the FP receptor could be used to design receptor antagonists. Applicants, therefore, assert that there is nothing in either Lake or Rehwald, alone or in combination to suggest the claimed antagonists. Furthermore, neither of the cited references provide any motivation to a skilled reader to combine the teachings therein in order to generate FP antagonists.

As indicated above, in order to expedite prosecution of the instant application, applicants have amended claim 1 to indicate that the claimed antagonists consist essentially of an amino acid sequence derived from the second extracellular loop of a prostaglandin F2 receptor. For the reasons set forth above, applicants assert that Lake and Rehwald do not teach or suggest antagonists of a FP receptor derived from the sequence of an extracellular loop of a FP receptor.

Finally, with regard to the Examiner's assertion that any FP receptor with a point mutation or a truncated or chimeric FP receptor would likely meet the limitations of claims 1 and 5, applicants submit that claim 1, as amended, does not encompass mutant truncated or chimeric FP receptors. Accordingly, applicants submit that the subject matter of claims 1 and 5 is not obvious in light of the combination of Rehwald and Lake, and respectfully request reconsideration and withdrawal of the 35 U.S.C. §103 rejection to the claims on this ground.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4591-4000. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4591-4000. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: July 20, 2004 By: 

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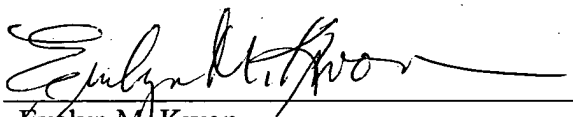
MORGAN & FINNEGAN, L.L.P.

Dated: July 20, 2004 By: 

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